

REMARKS

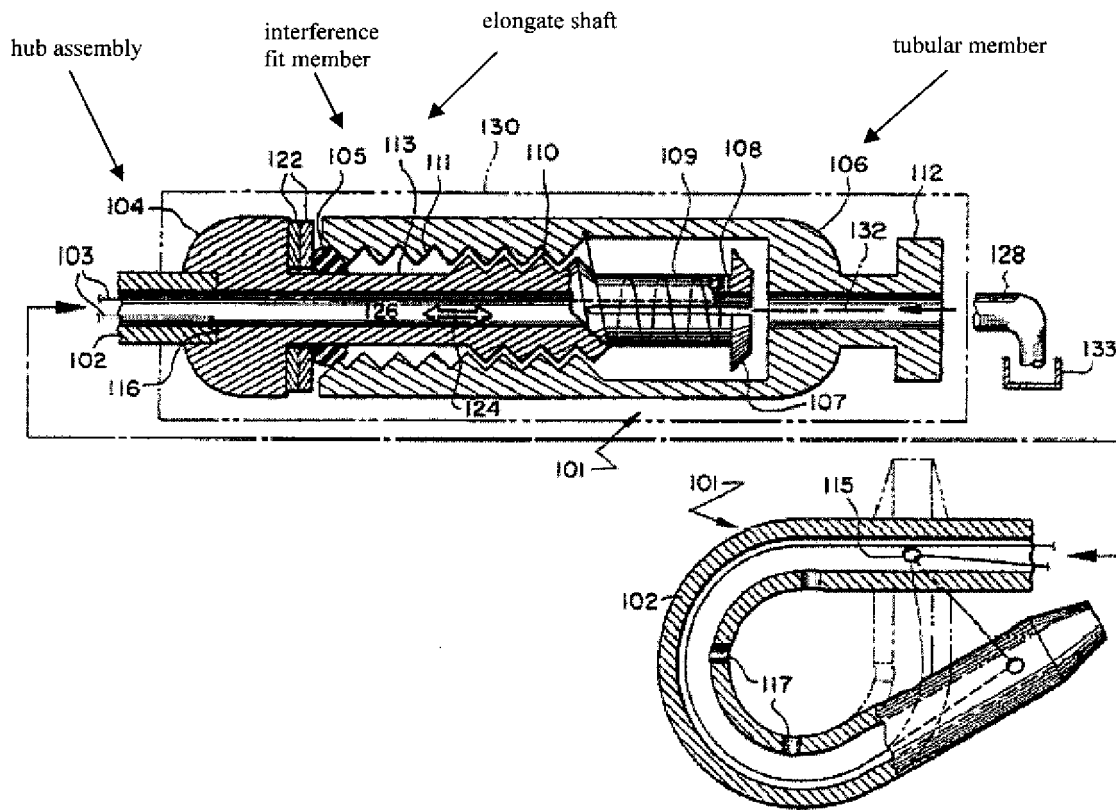
Applicant has carefully reviewed the Office Action mailed July 31, 2008, prior to preparing this response. Currently claims 1-26 are pending in the application, wherein claims 1-4, 7-13, 19-21 and 24-26 have been rejected and claims 5, 6, 14-18, 22 and 23 have been withdrawn. Claims 14-18, previously withdrawn, have been cancelled with this paper. In cancelling these claims, Applicant reserves the right to pursue these claims, or claims of a similar scope in a divisional application. No new material has been added. Favorable consideration of the above amendments and following remarks is respectfully requested.

Claim Rejections under 35 U.S.C. § 102

Claims 1, 7-13 and 26 stand rejected under 35 U.S.C. §102(b) as being anticipated by Roll (U.S. Patent No. 5,419,764). Applicant respectfully traverses this rejection.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). (MPEP 2131).

The Examiner asserts that Roll discloses elongate shaft 113, hub assembly 104 connected to the elongate shaft, and interference fit member 105 including a second material and disposed about a portion of hub assembly 104. Applicant respectfully disagrees with the Examiner's assertion. Fig. 1 of Roll is reproduced below, including notation to the elements of the device of Roll equated to the claimed elements.



Independent claims 1 and 26 both include the limitation “an interference fit member including a second material disposed about at least a part of the portion of the hub assembly including the first material”. Roll does not disclose this feature.

Roll discloses an O-ring 105 disposed about shaft 113 (see column 3, lines 51-52), between members 104 and 106. The shaft 113 is the feature of Roll, relied on in formulating the rejection, as being equated to the claimed elongate shaft, not the hub assembly. As such, Applicant suggests that O-ring 105 may be considered to be disposed adjacent to member 104 (which the Examiner asserts a being “the hub assembly”), but strongly disagrees with the Examiner’s assertion that the O-ring is disposed about member 104, as claimed.

Roll does not disclose all elements of independent claims 1 and 26. Therefore Roll cannot anticipate claims 1 and 26. Since claims 7-13 depend from claim 1, and add additional

elements thereto, Roll cannot anticipate these dependent claims either. Applicant respectfully requests that the rejection be withdrawn.

Claim Rejections under 35 U.S.C. § 103

Claims 1-4, 7-11, 13, 19-21 and 24-26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over McGlinch et al. (U.S. Patent No. 7,214,220), in view of Gadberry et al. (U.S. Patent No. 5,217,114). Applicant respectfully traverses this rejection, asserting a *prima facie* case of obviousness has not been established.

The Examiner admits that McGlinch et al. do not provide all elements of independent claims 1, 19, and 26. The Examiner asserts that it would be obvious to use “IFM (65)” of Gadberry et al. to provide an air tight seal when enclosing the device as taught by Gadberry et al. However, it is unclear to Applicant what would lead a person skilled in the art to look to the device disclosed by Gadberry et al. in order to arrive at the claimed features, particularly since the asserted air tight seal is not claimed or explicitly specified. The Examiner asserts Gadberry et al. disclose a similar elongate medical device (12) suitable for packaging in a tubular member (23) with an IFM (65) including a second material. In formulating the rejection, Applicant believes that the Examiner has mischaracterized what the art teaches.

O-ring 65 disclosed by Gadberry et al. is not a part of catheter 12 at all. Instead, Gadberry et al. disclose catheter 12 and catheter package 10, including tube 23, housing 25, and cap 27, such that O-ring 65 is used to form a seal between cap 27 and housing 25 of catheter package 10. Catheter 12 does not have any contact with O-ring 65. Accordingly, O-ring 65 cannot provide an interference fit between catheter 12 and catheter package 10. There is not any

reference or contemplation of an O-ring or interference fit member between the medical device and the packaging.

Applicant submits that just because the teachings of McGlinch et al. and Gadberry et al. could be or can be combined, does not render the combination proper under § 103. In *KSR Int'l Co. v. Teleflex Inc.* (550 U.S. __ 2007), the Court stated:

[A] patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art. Although common sense directs caution as to a patent application claiming as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does. Inventions usually rely upon building blocks long since uncovered, and claimed discoveries almost necessarily will be combinations of what, in some sense, is already known.

See page 14 of the April 30, 2007 Slip Opinion. In quoting *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006), the Court stated:

“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”.

Emphasis added; see page 14 of the April 30, 2007 Slip Opinion. The Court made clear that an obviousness rejection requires some articulated reason of why one skilled in the art would have been prompted to combine the elements in the claimed manner. Applicant submits that the Examiner's stated rationale does not meet the required threshold, and instead, is a conclusory statement.

For at least the reason that the asserted combination is improper, Applicant believes that all claims rejected by the Examiner under 35 U.S.C. §103(a) are indeed patentable over the cited combination. Additionally, Applicant believes that the Examiner has not considered all of the words in the claims in view of the cited combination.

*** “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).” (MPEP 2143.03).

More specifically regarding independent claim 1, the Examiner admits that McGlinch et al. do not disclose the IFM including a second material, and turns to Gadberry et al., who the Examiner asserts discloses “a similar elongate medical device (12) suitable for packaging in a tubular member (23) with an IFM (65) including a second material”. As discussed above however, Gadberry et al. clearly does not appear to disclose “an interference fit member including a second material disposed about at least a portion of the hub assembly” of a medical device, but instead appears to show an O-ring disposed between the cap and housing of a catheter packaging. Therefore, claim 1 is believed to be patentable over the cited combination. Since claims 2-4, 7-11 and 13 depend from claim 1 and add additional elements thereto, claims 2-4, 7-11 and 13 are also believed to be patentable over McGlinch et al. in view of Gadberry et al. Applicant respectfully requests that the Examiner withdraw the rejection.

Regarding independent claim 19, the Examiner admits that McGlinch et al. do not disclose the hub assembly including a circumferential channel and the IFM being disposed about a portion of the circumferential channel and comprising an elastomeric material, and turns to Gadberry et al., who the Examiner asserts discloses “a similar elongate medical device (12) suitable for packaging in a tubular member (23) with an IFM (65) disposed about a circumferential channel (64) and comprising an elastomeric material”. As discussed above, Gadberry et al. do not disclose “a hub assembly including at least a portion manufactured from a first material...wherein the portion of the hub assembly manufactured from the first material

includes a circumferential channel...the circumferential interference fit member disposed about at least a portion of the circumferential channel” as claimed, but instead show an O-ring disposed between the cap and housing of a catheter packaging. Therefore, claim 19 is believed to be patentable over the cited combination. Since claims 20-21 and 24-25 depend from claim 19 and add additional elements thereto, claims 20-21 and 24-25 are also believed to be patentable over McGlinch et al. in view of Gadberry et al. Applicant respectfully requests that the Examiner withdraw the rejection.

Regarding independent claim 26, the Examiner admits that McGlinch et al. do not disclose the IFM including a second material, and turns to Gadberry et al., who the Examiner asserts discloses “a similar elongate medical device packaging assembly (10) having a tubular member (23) and an IFM (65) including a second material”. However, Gadberry et al. do not disclose “an interference fit member including a second material disposed about at least a part of the portion of the hub assembly including the first material” of a medical device, but instead show an O-ring disposed between the cap and housing of a catheter packaging. Therefore, claim 26 is believed to be patentable over the cited combination, and Applicant respectfully requests the Examiner withdraw the rejection.

Claim 12 stands rejected under 35 U.S.C. §103(a) as being unpatentable over McGlinch et al. in view of Gadberry et al. and further in view of Roll. Applicant respectfully traverses this rejection.

For at least the reason that claim 12 depends from independent claim 1, which the Applicant believes is allowable, and adds additional elements thereto, Applicant submits that claim 12 is also allowable. Applicant respectfully requests the Examiner withdraw the rejection.

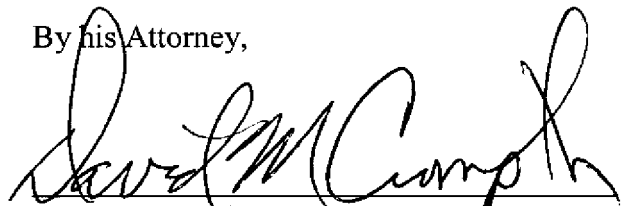
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

John Moberg

By his Attorney,

Date: 10/29/08

A handwritten signature in black ink, appearing to read "David M. Crompton", written over a horizontal line.

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